K023938

DEC 13 2002

SMDA Summary – Special 510(k) Modified Device

Submitted by:

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Contact Person:

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Summary Date:

November 18, 2002

Proprietary Name:

InSpectra™ Tissue Spectrometer System, Model 325

Common Name:

Tissue Spectrometer

CFR Reference:

21CFR§870.2700

Class:

II

Product Code:

74 MUD

Equivalent marketed device:

InSpectra™ Tissue Spectrometer System, Model 325, (K012759)

Device Description:

The **InSpectra™** is designed to estimate the percent oxygen saturation of hemoglobin in a volume of tissue (StO_2). This value is a reflection of localized perfusion of that tissue.

The **InSpectra™** is composed of the following components.

- Monitor: The "**InSpectra Tissue Spectrometer**" houses the user interface, and associated electronics. It serves as the analytical and display instrument.

- Patient Cable: The "**Optical Integrator**" transmits light to and from the Tissue Spectrometer and the patient;

- Patient Interface: The "**OptoShield™**" interface is a disposable pad that mechanically attaches to the distal end of the Optical Integrator. Its bottom has an adhesive backing for attachment to the patients skin for continuous monitoring. Until ready for use, the adhesive is covered with a liner to allow intermittent measurements.

- Printer: A "**Thermal Printer**" may be used to print out the StO_2 results for time trending and recording purposes.

- Optical Converter: An "**Optolink™**" RS232 Optical Converter - Model 300 is a device that converts the optical output of the Spectrometer to an electrical signal.

- Set-up Accessories: A "**System Check™**" module with both "High" and "Low" "**Single Point References**" are provided to verify proper system operation.

- Inspectra System Software: Software provided on a compact disk for use on a personal computer that displays data from the tissue spectrometer on a computer during a live session or from an encrypted data file.

Intended Use:

Hutchinson Technology Incorporated's InSpectra™ Tissue Spectrometer System, Model 325, is a non-invasive monitoring system that measures an approximated value of percent hemoglobin oxygen saturation in tissue (StO_2).

The InSpectra™ Tissue Spectrometer with 12 to 25 mm probes is indicated for use in monitoring patients during circulatory or perfusion examinations of skeletal muscle or when there is a suspicion of compromised circulation.

The InSpectra™ Tissue Spectrometer System is intended to noninvasively and continuously measure hemoglobin oxygen saturation: in the upper extremity, shoulder, or lower extremity with 12 mm to 25 mm probes.

The value of these measurements in disease states has not been demonstrated.

Technological Characteristics:

The modified device has the same basic technological characteristics as the predicate device. The modification includes:

New software provided via compact disk that can be downloaded onto a personal computer. The software enables the user to view, store and chart the output measurement of the Inspectra System. The software does not alter the information already displayed on the predicate device. There is a one-way communication from the monitor to the user PC.

Substantial Equivalence Rationale:

HTI believes that the modified device is substantially equivalent to the unmodified predicate device. The unmodified device already provides the capability to display information through its output device (Optolink) to a thermal printer.

The predicate to our unmodified Inspectra device was the Hutchinson Technology, Inc. Biospectrometer NB Model 1111, FDA control # K963903. The Biospectrometer used a laptop personal computer for the primary display of StO_2 and other output information including date and time, and allowed the data to be marked, saved and charted.

Test Conclusions:

Hutchinson Technology, Inc. has conducted extensive testing of the new Inspectra™ Software to verify adherence to requirements. All test results verify that the software meets or exceeds all predetermined specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 13 2002

Mr. Thomas A. Dold
Regulatory Affairs Manager
Hutchison Technology, Incorporated
BioMeasurement Division
40 West Highland Park Drive NE
Hutchinson, Minnesota 55350

Re: K023938
Trade/Device Name: InSprectra™ Tissue Spectrometer System, Model 325
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: MUD
Dated: November 18, 2002
Received: November 26, 2002

Dear Mr. Dold:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594- 4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

9.0 INDICATIONS FOR USE

Indications for Use Statement

K023938

Device Name:

InSprectra™ Tissue Spectrometer System, Model 325

Indications For Use:

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(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K023938

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____X____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)